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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,994	07/14/2003	Scott Cunningham	2848	5963

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UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/618,994

Applicant(s)

CUNNINGHAM ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/15/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 15 February 2007.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 6, lines 20-21 of the specification and Figures 5-7 the side surfaces **28** are not disclosed as "generally convex," and therefore the limitation is considered to be new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. Claims 1-2,10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) in view of **Otsuka et al.**, or **Otsuka** (U.S. Patent No. **5,178,628**).

Claim 1: Guido discloses an elongated needle body **10**, that defines a longitudinal y-axis and x and z axes transverse to the y-axis, and a central shaft **18** having a first end **22** and a second needled end **12** (Figure 2). The needled end **12** has lower and upper opposed surfaces and single side surfaces **70** extending continuously between the lower and upper surfaces and contiguous therewith, wherein the lower and upper surfaces start where the side surfaces begin, and the needle end having a transition area whereby the needle end defines a substantially trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges (Figures 9-11).

Guido discloses the claimed device except for the upper surface and side surfaces intersecting to define opposed first and second generally convex side cutting edges extending to a pointed tip and the lower surface extending to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip and the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body and terminating at the pointed tip, and the needle end having a transition area defining a substantially triangular transverse cross-sectional dimension inclusive of the first, second and third cutting edges and being distal of the transition area.

Otsuka teaches side surfaces **10b** and **10c** intersecting to define opposed first and second generally convex side cutting edges that extend to a pointed tip **4** and a lower surface of body portion that extends to a third cutting edge **11b** defined at the

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intersection of the side surfaces and proximal of the pointed tip, and also extends in oblique relation relative to the longitudinal axis of the upper surface **5a** (Figure 2 and col. 5, lines 35-40). Otsuka also teaches the needle end having a transition area defining a substantially triangular transverse cross-sectional dimension inclusive of the first, second and third cutting edges and being distal of the transition area in Figure 2, as well as a substantially substantially trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges and proximal the transition area. It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the convex side surfaces extending to a pointed tip that have the substantially triangular and trapezoidal cross-sections, as taught by Otsuka, to the device of Guido, since it was known in the art that needles should sharp as possible at the tip and must spread tissue out with the third edge and convex side surfaces in order to function properly, which is known in the art since sharper needles require less force and therefore less tissue trauma.

Otsuka also teaches that the third cutting edge that extends in oblique relation relative to the longitudinal axis (col. 5, lines 9-20). It would have been obvious to provide side surfaces extending to a pointed tip and the lower surface extending to a third cutting edge defined at the intersection of the side surfaces, which extends in oblique relation relative to the longitudinal axis, as taught by Otsuka, to Guido since it was known in the art that providing an angle of slope determines the rate at which tissues are cut, and therefore may be altered depending on the application and the particular tissue to be cut.

Claim 2: Guido discloses upper and lower surfaces **70** that are substantially planar (Figures 9-11).

Claim 10: Guido discloses a needle body that is curved along the longitudinal axis (Figure 2).

Claim 13: Guido discloses the side surfaces being each substantially planar (Figure 9).

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) and **Otsuka** (U.S. Patent No. **5,178,628**), as applied to Claim 1 above, and further in view of **Smith** (U.S. Patent No. **4,513,747**).

Claim 12: Guido and Otsuka lack a linear cutting edge intersecting the upper planar surface at an angle ranging from about 15 to about 30 degrees relative to the longitudinal axis.

Smith teaches an angle of slope **d** between the cutting edge **21** and upper surface **33** that ranges from about 15 to 30 degrees relative to the longitudinal axis (Figure 3, col. 5, lines 4-9). Smith teaches that this range of angles provides ease of passage of the need through the tissue (col. 3, lines 36-38). It would have been obvious to modify Guido with the linear cutting edge intersecting the upper planar surface at an angle ranging from 15 to about 30 degrees, as taught by Smith, to Guido and Otsuka in order for the needle to easily pass through tissue.

3. Claims 5-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) and **Otsuka** (U.S. Patent No. **5,178,628**), as applied to Claim 4 above, and further in view of **Munoz** (U.S. Patent No. **5,178,628**).

Claims 5-7 and 14: Guido and Otsuka disclose the claimed device including a substantially trapezoidal cross-sectional dimension, but lack a cross-sectional dimension defining a dimension along the z-axis corresponding to a first width of the needle end, which is at least equal to a corresponding shaft width of the central shaft, greater than a corresponding shaft width of the central shaft, and not less than about 1.5 times the shaft width and a needled end defining a maximum dimension along the z-axis greater than a corresponding maximum dimension along the z-axis of the central shaft.

Munoz teaches a surgical needle that has a cross-sectional dimension that defines a dimension along the z-axis corresponding to a first width of the needle end, which is at least equal to the corresponding shaft width of the central shaft, is greater than the corresponding shaft width, or a needled end defining a maximum dimension along the z-axis greater than a corresponding maximum dimension along the z-axis of the central shaft (Figures 5A-5C). Although the first width of Munoz is not disclosed as not less than about 1.5 times the shaft width, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the dimension of a first width of the needle end being at least equal to a corresponding shaft width of the central shaft, greater than a corresponding shaft width of the central shaft, as taught by Munoz, and not less than about 1.5 times the shaft width, to the combined device of Guido and

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Otsuka since it was known in the art that the needle end would produce a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily.

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**), **Otsuka** (U.S. Patent No. **5,178,628**), and **Munoz** (U.S. Patent No. **5,178,628**), as applied to Claim 6 above, and further in view of **Naslund** (U.S. Patent No. **4,133,339**).

Claims 8-9: Guido, Otsuka, and Munoz disclose the claimed device including a substantially trapezoidal cross-sectional dimension, but lack having the cross-sectional dimension defining a dimension along an x-axis corresponding to a first height of the needle end, the first height being less than a corresponding shaft height of the central shaft, and not greater than about 0.5 times the shaft height.

Naslund teaches a needle capable of holding sutures that has a thickness ("first height") around a first portion **303**, which is perpendicular to the width (col. 3, lines 27-29), that is less than a corresponding shaft portion **307** and not greater than about 0.5 times the shaft thickness. Naslund teaches that the diminished thickness allows for a corresponding increase in the thickness, and therefore an increase in rigidity of the needle (col. 2, lines 17-21). It would have been obvious to modify Guido, Otsuka, and Munoz with the thickness dimension less than a corresponding shaft portion and not greater than about 0.5 times the shaft thickness, as taught by Naslund, because it allows an increase in the thickness of the needle and adds to the rigidity of the needle.

5. Claim 11 rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) and **Otsuka** (U.S. Patent No. **5,178,628**), as applied to Claim 10 above, and further in view of **McGregor et al.** (U.S. Patent No. **4,524,771**).

Claim 11: Guido and Otsuka disclose the claimed device except for the elongated needle shaft defining an angle of curvature ranging from about 80 to about 180 degrees.

McGregor et al. discloses an elongated needle shaft **25** with an angle of curvature within the range of about 80 to about 180 degrees. McGregor et al. teaches that the curve in the needle is helpful in placing the suture by allowing the surgeon to grasp the body of the needle near its center and allows the suture to be placed at a desired depth by a controlled emergence of the needle from the tissue (col. 1, lines 9-24). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an angle of curvature ranging from about 80 to about 180 degrees to the elongated needle shaft, as taught by McGregor et al., to the combined device of Guido and Otsuka in order to facilitate placing the suture in the tissue to be closed at a desired depth.

6. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**) in view of **Otsuka** (U.S. Patent No. **5,178,628**) and **Munoz** (U.S. Patent No. **5,762,811**).

Claim 15: Guido discloses an elongated needle body **10**, that defines a longitudinal y- axis and x and z axes transverse to the y-axis, and a central shaft **18** having a first

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end **22** and a second needled end **12** (Figure 2). The needled end **12** has lower and upper opposed surfaces and single side surfaces **70** extending continuously between the lower and upper surfaces and contiguous therewith, wherein the lower and upper surfaces start where the side surfaces begin (Figure 9). Guido also discloses the needle end having a transition area whereby the needle end defines a substantially trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges (Figures 9-11).

Guido discloses the claimed device except for the upper surface and single side surfaces intersecting to define opposed first and second generally arcuate side cutting edges extending to a pointed tip and the lower surface extending to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip and the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body and terminating at the pointed tip, the second needled end defining a maximum dimension inclusive of the first and second cutting edges greater than a corresponding maximum dimension of the central shaft, and the second needle end having a transition area defining a substantially triangular transverse cross-sectional dimension inclusive of the first, second and third cutting edges and being distal of the transition area.

Munoz teaches single side surfaces intersecting to define opposed first and second generally arcuate side cutting edges that extend to a pointed tip and a lower surface of body portion that extends to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip, and also extends in oblique relation

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relative to the longitudinal axis of the upper surface (Figures 5A-5C). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the side surfaces extending to a pointed tip, as taught by Munoz, to the device of Guido, since it was known in the art that needles should sharp as possible at the tip and must spread tissue out with the arcuate side surfaces in order to function properly, which is known in the art since sharper needles require less force and therefore less tissue trauma.

Munoz also teaches that the cutting edge that extends in oblique relation relative to the longitudinal axis serves as an angle of slope which determines the rate at which tissues are cut, and therefore may be altered depending on the application and the tissue to be cut (Figures 5A-5C). It would have been obvious to provide side surfaces extending to a pointed tip and the lower surface extending to a cutting edge defined at the intersection of the side surfaces, which extends in oblique relation relative to the longitudinal axis, as taught by Munoz, to Guido since it was known in the art that providing an angle of slope determines the rate at which tissues are cut, and therefore may be altered depending on the application and the particular tissue to be cut.

Otsuka teaches the needle end having a transition area defining a substantially triangular transverse cross-sectional dimension inclusive of the first, second and third cutting edges and being distal of the transition area in Figure 2, as well as a substantially substantially trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges and proximal the transition area. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a transition

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area of substantially transverse cross-sectional dimension, as taught by Otsuka, to Guido since it was known in the art that having this configuration also provides more edges to more easily cut tissue and provides an angle of slope that determines the rate at which tissues are cut, therefore allows for a controlled force for cutting.

Claim 16: Guido discloses the side surfaces being each substantially planar (Figure 9).

Claim 17: Guido discloses the claimed device except for the third cutting edge being substantially linear.

Munoz teaches a third cutting edge being substantially linear (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a substantially linear third cutting edge, as taught by Munoz, to Guido since it was known in the art that a linear cutting edge permits long cutting action and less likelihood of bending or deformation of the tip.

Claim 20: Guido discloses the claimed device except for the maximum dimension of the second needled end is at least about 1.5 times the maximum dimension of the central shaft.

Although Munoz does not disclose for the maximum dimension of the second needled end is at least about 1.5 times the maximum dimension of the central shaft, it would have been obvious to one of ordinary skill in the art to modify Guido with this dimension since it was known in the art that the needle end would produce a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily.

Response to Arguments

7. Applicant's arguments filed 15 February 2007 have been fully considered but they are not persuasive.

8. Applicant's arguments with respect to Claim 1 have been considered concerning the new limitation in the amended Claim 1, but are moot in view of the new ground(s) of rejection.

9. Applicant generally argues that Guido '397 teaches away from incorporating cutting edges in a needle end leading to a pointed tip and that there would be no motivation to combine the teaching of Otsuka '628, which is a needle end having surfaces and cutting edges extending to an extreme pointed tip, to Guido '397.

The examiner disagrees. Guido '397 appreciates that its needle **10** should "easily penetrate and smoothly pass through the tissue being sutured" in order to "minimize the resistance of the tissue to the passage of the entire needle through the tissue" (col. 1, lines 15-19), while also reducing the likelihood of penetrating the glove and skin of a user "by making a less sharper point" (col. 2, lines 1-11). The needle of Guido '397 does have a gradually decreasing cross-sectional shape towards its distal end to a "pointed tip" as recited in Claim 1, and therefore the needle of Guido '397 reads on this limitation. In other words, Guido '397 does not teach away from a pointed or sharp tip, but rather having a less sharper point would require more initial applied force to the needle for penetration, while still being sharp enough to smoothly pass through tissue. The modification of Guido '397 with Otsuka '628 is necessitated by the lack of a third cutting edge at the intersection of two convex side edges which terminate at a

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pointed tip in Guido '397, rather than the fact that Guido '397 lacks "an extreme pointed tip" as in Otsuka '628. As maintained above, it would have obvious to modify Guido '397 with Otsuka '628 since it was known in the art that needles should be as sharp as possible to avoid tissue trauma, while still reducing the probability of skin penetration of the operator, and convex side surfaces effectively spread tissue out while the tip moves into the skin.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M. J. Hayes", with a stylized, flowing script.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER